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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,262	05/10/2006	Petra Peters-Wendisch	23369	5108
535	7590	09/07/2007		
K.F. ROSS P.C. 5683 RIVERDALE AVENUE SUITE 203 BOX 900 BRONX, NY 10471-0900			EXAMINER MEAH, MOHAMMAD Y	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,262	<b>Applicant(s)</b> PETERS-WENDISCH ET AL.	
	<b>Examiner</b> Mohammad Meah	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 9-13, 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/12/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

With preliminary amendment of this application, the applicant, on date 5/29/07 elected with traverse Group I (claims 1-8 and 14-20) for examination.

### ***Election/Restriction***

During preliminary amendment of this application, the applicant, on date 5/29/07 elected with traverse elected with traverse Group I (claims 1-8 and 14-20) directed to a nucleic acid having a mutated nucleotide 506-918 of SEQ ID NO:1 that encode L-serine dehydratase, vector and transformant for examination.

Groups II-III (claims 9-13 and 21-24 ) of election/restriction-office action of date 02/25/2007 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups.

Applicants' arguments that a common technical feature ( gene and protein belong to L-serine dehydratase) exist in all these groups is considered but not found persuasive. Nucleic acid and protein belong to different class of compound having different structure, function and utilities. This common technical feature is not a special technical feature as Lovinger et al. (US pat 4528273) teach this feature, therefore, restriction is applied under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding

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special technical features as explained in prior office action. Therefore the restriction is maintained and made FINAL.

### ***Priority***

Acknowledgement is made of applicant's PCT priority date based on application filing date of 02/12/2004 in Germany # PCT/DE04/00248 and foreign priority filing date 03/03/2003 # Germany 10311399.1.

### ***Claim Objections***

Claims 1, 16 the word "replicable" needs to be corrected as this word is misspelled. Appropriate correction is required.

Claims 1, 14 the phrases "nucleotide sequence coding" or "nucleotide sequence which codes" should be "nucleotide sequence encoding" or "nucleotide sequence which encodes". Appropriate correction is required.

Claims 1, 2 the word "lesser" needs to be corrected as this is improper English. Appropriate correction is required.

Claim 3 "form position" needs to be corrected to "from position"  
Appropriate correction is required.

### ***Claim Rejection***

**35 U.S.C 112**

Claims 1-8, 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6, 14-15, 17-20 are indefinite as the recitation of "characterized in that—" make the claims indefinite and vague. It is unclear whether the claims are limited to what follows this phrase or if what follows is merely exemplary of some larger group.

Claims 1-2 are indefinite in the recitation of "lesser extent-- naturally occurring sequence" make the claims indefinite and vague. Less than what? And what is the naturally occurring sequence .

Claim 1 is indefinite in the recitation of "coding for serine dehydratase which is partially or completely mutated" - make the claims indefinite and vague. If completely mutated what is present therein?

Claim 2 is indefinite in the recitation of "sdaA gene sequence is partially or completely deleted or mutated" - make the claims indefinite and vague. If completely deleted or mutated what is present therein?

Claim 3 is indefinite in recitation of "homolog", "derivative" as it is unclear how similar to SEQ ID NO: 1 a "homolog" or "derivative" must be.

Claim 3 is indefinite in recitation of "hybridizing" as it is unclear what is the hybridizing condition as different hybridization conditions yield different DNA products.

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Claims 14-15 are indefinite in the recitation of “reduced extent—” make the claims indefinite and vague. It is unclear what is reduced.

Claim 16- the recitation of “according to containing” makes the claim indefinite as “according to containing” is meaning less.

Claims 18-19 are indefinite in the recitation of “-it brings to the family-” make the claims indefinite and vague. It is unclear what “-it brings to the family-” means. Rewrite the claims so that they make sense.

Claim 20 is rejected because the stated claim not make any sense. Rewrite the claim 20 so that it makes sense.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 14-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of nucleic acid molecule variant of SEQ ID NO:1 encoding a protein with reduced or no serine dehydratase activity and vector and transformed bacterium containing said DNA. The specification teaches the structure of only a single representative species of such DNA ( mutated SEQ ID

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NO:1 wherein one or more residues from position 506-918 of SEQ ID NO is deleted). Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than having reduced/not having l-serine dehydratase activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-8, 14, 16-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This claim is directed to a genus of variants of the DNA molecules of SEQ ID NO: 1 having reduced/no serine dehydratase activity compare to SEQ ID NO:1. The specification does not contain any disclosure of the function of all DNAs encompassed in said genus. The genus of cDNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of the claim. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 1-8, 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the mutated DNA of SEQ ID

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NO: 1 wherein one or more residue from 506-918 are mutated so that said DNA shows no or reduced *sdaA* activity from unmutated SEQ ID NO: 1, does not reasonably provide enablement for any DNA or DNA molecule that hybridize with any mutant of SEQ ID NO:1. encoding any protein and vector and transformant transformed by said DNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims are 1-8, 14-20 so broad as to encompass any DNA or DNA molecule that hybridize with any mutant of SEQ ID NO:1. encoding any protein and vector and transformant transformed by said DNA. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number DNAs broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the mutant nucleotide of SEQ ID NO: 1 encoding a protein having reduced *sdaA* activity.



While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims, which encompass any DNA, or DNA molecule that hybridize with any mutant of SEQ ID NO:1. encoding any protein and vector and transformant transformed by said DNA because the specification does not establish: (A) regions of the protein structure which may be modified to eliminate or reduce *sdaA* activity; (B) the general tolerance of *sdaA* gene to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any *sdaA* nucleotide residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA or DNA molecule that hybridize with any mutant of SEQ ID NO:1. encoding any

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protein and vector and transformant transformed by said DNA. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of sdaA genes, having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

### ***CLAIM Rejection - 35 U.S.C 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,4-8, 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubota et al. (Agr.biochem 1985, from ids). Kobuta et al. teaches mutant gene having reduced sdaA activity and corynform bectria expressing said mutant gene.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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